

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WSG 53

Date Signed: December 27, 1989

Revised: December 1998

Revised by: Wendy Warren

MEMORANDUM

SUBJECT: Analytical Methods for Compliance and Limited
Alternate Test Procedures Approvals

FROM: Michael B. Cook, Director (signed by A. Kuzurade, Acting)
Office of Drinking Water, WH-550D

TO: Environmental Services Division Directors
Regions I-X

For many years, limited alternate test procedures (ATPs) for drinking water compliance analyses have been approved by the Office of Drinking Water (ODW) after favorable review by the Environmental Monitoring Systems Laboratory (EMSL), under 40 CFR 141.27. The petitions were usually initiated by a single laboratory and were forwarded by the State to EMSL. The approval extended only to the specific laboratory approved by the petitioning State, thus, the "limited" status.

There are several problems with this procedure. 40 CFR 141.27 Alternate Analytical Techniques reads:

"With the written permission of the State, concurred in by the Administrator, an alternate analytical technique may be employed..."

A careful reading of 40 CFR 141.27(a) indicates that only the Administrator has the authority to approve an alternate analytical technique after a request from the State. According to the Office of General Counsel (OGC), there is no officially delegated authority to the ODW Director to grant these approvals. Apparently, a delegation was never sought when Sec. 141.27 was promulgated in 1980. This raised a question of the validity of past approvals, and leaves the ODW Director without authority to issue new approvals. This authority was not officially delegated to any Regional official.

Furthermore, OGC has advised that, under the SDWA, compliance analyses must be performed utilizing methods listed in the regulations and that any changes to the regulations must be processed through the normal rulemaking procedure. In OGC's opinion, Section 1450 of the SDWA prohibits the Administrator from delegating this authority to anyone.

Section 1450(a) of SDWA reads:

"(1) The Administrator is authorized to prescribe such regulations as are necessary or appropriate to carry out his functions ..."

"(2) The Administrator may delegate any of his functions under this title (other than prescribing regulations) to any officer or employee of the Agency..."

There are also philosophical problems with continuing this process. The advisability of allowing a single lab to deviate from the national uniform regulations is questionable. This may have been a useful mechanism to allow for the use of newer techniques and methods adapting for unusual matrixes between 1980 and 1987. However, since 1987, we have been actively revising all the regulations, including examining all appropriate methodologies.

For the above reasons, ODW will no longer consider and approve limited ATPs, and will propose to repeal 40 CFR 141.27. In place of the limited ATP procedure, ODW is establishing a two-tiered system for rapidly adopting new and revised analytical technologies for use by all laboratories.

The first tier is for new methods, significantly modified methods or new applications of currently approved methods. These will be evaluated by EMSL and become candidates for accelerated regulation development. This is important because laboratory technology is changing rapidly and we should be as close to the cutting edge as the data will allow. Through formal proposal, public comment and promulgation in the Federal Register, the list of methods approved for use under the regulations will be amended accordingly, thus making appropriate changes available to all laboratories. ODW expects to be able to process changes at least as frequently as twice per year.

The second tier covers minor improvements to existing methods which are optional and do not substantially alter the method. These will also be evaluated by EMSL and become candidates for inclusion in periodic Federal Register notices. Rather than formally amending the regulations, this notice will interpret the existing regulatory methods to include the minor optional changes. Analysts may use these minor changes or continue to use the methods as originally promulgated. The relatively minor adjustments that will be made through this process (i.e., matrix modifications, alternates to extraction specifications, preservation changes, etc.) have been the subject of many ATP applications received in the past. Hence, the need for ATPs will be greatly reduced.

This new two-tiered process provides an avenue for evaluating all methodology changes which were handled under the old alternate test procedures program. The new streamlined system will be more desirable because it will:

- ! rapidly update NPDWRs to include the latest analytical technologies;
- ! make changes available to all laboratories;
- ! allow everyone to benefit from the changes;
- ! provide for a more uniform system for compliance determinations; and

! allow for ease of enforcement.

Please share this information with the State program and laboratory directors. If you have any questions or need further information, please contact Herb Brass on (513) 569-7936.

cc: Water Division Directors, Regions I-X
Tom Clark, EMSL-CI
Lee Schroer, OGC
Bob Blanco, SPD
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***Note: Guidance will need to be updated after PBMS revisions are finalized.**